REMARKS

STATUS OF THE CLAIMS

Claims 1, 3, 4, 7, 8, and 14 – 21, as amended, and new claims 22 – 24 are pending in the application. Claims 2, 5, 6, and 9 – 13 are canceled. Claim 1 has been amended to cover the treatment of high bone turnover caused by osteomalacia or drug-induced high bone turnover rather than bone turnover caused by any means. The measurement step has been moved to new dependent claim 24. Support for the amendment to claim 1 and new claims 22 and 23 may be found in the specification at parapgraph [004]. New claims 14 – 21 have been added. Therefore, no new matter is presented.

Applicants reserve the right to prosecute the deleted subject matter in continuation applications.

Reconsideration and re-examination of this application in view of the above amendments and the following remarks is herein respectfully requested.

REJECTION OF CLAIMS 1 AND 3 – 5 UNDER 35 U.S.C. §103(a)

Claims 1 and 3 – 5 and 7 – 21 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Marttunen et al., Calcified Tissue International, 65:365-368 (1999) taken with Kangas, Cancer Chemotherapy and Pharmacology, 27:8 – 12 (1990) in view of Fukumitsu et al., Metabolism 51(7), 814-818 (2002), Lindberg et al., Journal of Endocrinology (2001) 171, 229 – 236, and Suda et al., The Journal of Immunology 2004, 172:2504-2510. This rejection is respectfully traversed.

The Examiner relates that Marttunen et al. teaches the administration of toremifene to ascertain bone resorption in postmenopausal breast cancer patients by measuring bone resorption markers. The Examiner admits that Marttunen fails to teach the compounds of formula (I), the specific bone markers measured in some of the dependent claims and the specific dosages claimed in claims 15 – 17 and 19 – 21. The Examiner cites the Kangas reference to show the metabolites of toremifene were known. Fukuitsu et al. is cited as teaching a the bone resorption marker, type 1 collagen-cross-linked N telopeptide in urine although the marker is used to diagnose bone metastasis in

prostate cancer patients. Suda and Lindberg are cited as allegedly teaching the use of TRAP-5b in bone resorption assays. Crofton is cited as teaching the use of the marker Crosslaps in both serum and urine in children and postmenopausal women.

The Examiner concludes that one would have been motivated to administer TORE VI to individuals suffering from increased bone turnover or bone loss and further one would be motivated to use Crosslaps and TRAP5b as assaying methods to determine bone resorption in patients.

Without acquiescing to the rejection, Applicants first point out that claim 1 has been amended. It does not cover any type of high bone turnover. Rather, it covers a method of treating an individual suffering from increased bone turnover caused by osteomalacia or drug-induced high bone turnover. Applicants respectfully point out that none of the cited references, either alone or in combination, teaches or suggests a method of treating an individual suffering from increased bone turnover caused by osteomalacia or drug-induced high bone turnover. None of the cited references specifically teaches the administration of ospemifene (or any of the compounds of formula I) for any disease, much less the specific diseases named in the current claims.

The Marttunen et al. reference may teach the administration of toremifene to breast cancer patients, but it does not teach or suggest the administration of ospemifene to treat osteomalacia or drug-induced high bone turnover. Further, Kangas may suggest that the metabolite now known as ospemifene was biologically active, but did not teach or suggest that it was suitable in the treatment of any particular disease. The remaining references (Fukumitsu et al., Suda et al., Lindberg et al., and Crofton et al.) merely relate to markers and assays and do not provide the necessary motivation for one to administer ospemifene to treat osteomalacia or drug-induced high bone turnover.

The Examiner must provide a reason or motivation as to why one of ordinary skill in the art would select ospemifene (or any compound of formula (I)) as a starting point to treating osteomalacia or drug-induced high bone turnover. There is no teaching or suggestion in the cited art to use a metabolite of toremifene, a cancer drug, to treat osteomalacia or drug-induced high bone turnover. Applicants respectfully submit that the

rejection is deficient in teaching or suggesting the claimed invention as amended and should be reconsidered and withdrawn.

Applicants thank the Examiner for her consideration of this case and submit that the case is in condition for immediate allowance. If the Examiner believes that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at 734-302-6042.

Respectfully submitted,

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